

REMARKS

1. **Status Of The Claims.** Claims 1, 5-12, 15, 16, 18, 21, 150, 151, 154 and 155 are pending in the subject application. Applicant notes that the Examiner has not listed claim 154 in the Office Action Summary which is pending and Applicant assumes that claim 54 listed is actually claim 154.

Claims 2-4, 13-14, 17, 19-20, 22-149, 152, and 153 have been without prejudice canceled. Applicant respectfully reserves the right to pursue any non-elected claims, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Claims 1 and 5 has been amended without the addition of any new matter.

Claims 15, 18, 150, 151, 154, and 155 have been previously presented.

Claims 6, 7, 8, 9, 10, 11, 12, 16 and 21 are as originally presented.

2. **Interview Summary.** Applicant and Examiner conducted a telephonic interview on June 4, 2010 with respect to the priority date and whether certain references were effective in view of the priority date or whether Applicant could swear behind or show that the references were not of "another". The Examiner advised Applicant that certain claim limitations were not supported by the priority document. Applicant indicated a belief that the priority document did provide support for the claims as amended in the response filed March 22, 2010 but would review the priority document and by way of this office action respond.

3. **The Rejections Under 35 U.S.C.A. Section 112, First Paragraph, Are Overcome.** In the present application, the Examiner has rejected claims 5-12, 15, 16, 18, 21, 150, 151, 154, and 155 as failing to comply with the written description requirement.

The Examiner asserts that Applicant teaches “incubating at temperatures between about 5°C and about 25°C and staining at 34°C for either 30 or 60 minutes.”

Applicant understands that Examiner asserts that the phrase “at temperature above the temperature at which sperm cells transition from a liquid phase to a gel phase” is new matter. Applicant has amended claim 1 to remove this phrase.

Applicant notes that US60/400,486 (the “486 application”) on which the instant application claims benefit specifically states that “the sperm cell process system can involve. . .maintaining the sperm cells obtained from the male species of mammal at temperature(s) selected within the range of between 5°C and 25 °C. . .” 60/400,486 at Page 7 (*emphasis added*). Additionally, the ‘486 application provides specific examples in the claimed range of between about 10°C and to about 20°C and specifically 15°C and of about 20°C which certainly support the entire range, any selected portion of the range, the language of above 5 °C and about 25 °C, or any other portion of the range or temperature selected within the range of between 5 °C and about 25°C.

Applicant respectfully requests that the Examiner withdraw the rejection based on Section 112, first paragraph in regard to the prior amended claim language of “above 5 °C and 20°C, or in regard to the currently amended language of claim 1 which recites about 7 °C and about 25 °C.

Additionally, Applicant understands that the Examiner asserts that US 60/400,486 only teaches a staining time of either 30 minutes or 60 minutes. Applicant points out that the ‘486 application does provide Examples in which the staining time is 30 minutes and provides Examples in which the staining time is 60 minutes (see Example 5, Page 11 and Table 8 and Table 9); however, the ‘486 application also states that “stain time can be substantially reduced without the loss of resolution between X-chromosome bearing populations and Y-chromosome bearing populations of sperm cells evaluated by flow cytometry” and “the invention can further include the step of reducing time in which sperm cells are incubated in the stain solution to reduce % dead in stained sperm samples or to increase motility, or increase resolution of X-

chromosome bearing stained sperm from Y-chromosome bearing stained sperm when flow sorted. . .the reduction in time can be 10%, 20%, 30%, 40%, 50% or more . . .can be between about 25 minutes to about 50 minutes to obtain greater flow sorting resolution or reduced % dead sperm cells, and can be specifically 30 minutes.” *US 60/400,486 at Pages 14 and 15.* Accordingly, the ‘486 application teaches that the staining time can be incrementally adjusted between 30 minutes and 60 minutes (and can as to certain embodiments be a time lesser than 30 minutes).

Applicant respectfully requests that the Examiner withdraw any rejection based on Section 112, first paragraph, in regard to the use of the range “about 25 minutes to about 50 minutes” as set out in claim 1.

The Examiner also indicates that there is no support for staining at any other temperature above the temperature at which sperm cell membranes lipids transition from liquid to gel phase. It is clear from the ‘468 application that time and temperature in certain Examples is held constant (at a constant time of 30 minutes or at 60 minutes or at a constant 34 °C) such that the results of the experimental variables tested can be quantitatively assessed.

A person of ordinary skill in the art affording a reasonable interpretation to the teachings of the ‘486 application would understand that the temperature is not fixed except for the purpose of providing a control for assessing the effect of the experimental parameters and that the temperature can vary in accordance with the conventional staining method employed and that the staining time can be reduced in accordance with incubation and staining steps of the claimed invention to confer the advantages taught by the ‘468 application.

This interpretation is consistent with the ‘468 application which teaches that the reduction in time depends upon the application (*bottom of page 14*) and can reduce the amount of time typically used (*top of page 15*). *US 60/400,486 at Pages 14 and 15.* The ‘468 specification broadly states the advantages of “decreasing the incubation period to stain sperm cells. . .can increase motility, decrease percent dead sperm cells, and increase resolution of X-chromosome

bearing sperms cells from Y-chromosome bearing sperm cells.” *US 60/400,486, Page 14 and Figure 4 which does not fix the temperature at which the staining step can occur.*

Applicant respectfully requests that the Examiner withdraw any rejection based on Section 112, first paragraph, in regard to the range of temperatures conventionally used to stain sperm cells which are certainly supported by the ‘468 reference.

2. The Seidel Reference Must Be Withdrawn Because Applicant’s Priority Date Falls Before the Publication Date Of The Seidel Reference. In the prior response submitted March 22, 2010, Applicant submitted evidence that the reference entitled “Current Status of Sexing Mammalian Spermatozoa” by Seidel et al. was published on December 1, 2002 (including then submitted Exhibit A). Applicant’s priority date based on United States 60/400,486 is July 22, 2002. Applicant believes that the claims as currently amended are supported by the ‘486 application as explained by the above remarks. Accordingly, Applicant respectfully requests that the Examiner withdraw the Seidel reference.

4. The Rejections Under 35 U.S.C.A. Section 102 Are Overcome. In the present application, the Examiner rejected claims 1, 5, 6, 9-12, 15, 18, 21, and 150 as being anticipated by either of two references by Lindsey, or WO00/06193, or Theriogenology, vol. 53, p. 133-1344 (“Buchanan”).

Applicant Swears Behind the Lindsey References. The Examiner rejected claims 1, 5, 6, 9-12, 14, 16, 18, 21, and 150 based on each of Lindsey et al. (Equine Vet. Journal, March 2002, p. 128-132) and Lindsey et al. (Equine Vet. Journal, March 2002, p. 121-127) (the “Lindsey references”).

Applicant submits a Declaration of the inventors Lindsey and Schenk under 37 C.F.R. §1.131(a) which evidence that the inventors conceived of the claimed invention and through a series of experiments reduced to practice the claimed invention prior to the publication of the Lindsey references. *See Declaration Under 37 C.F.R. §1.131(a) of Allison Lindsey and John*

Schenk along with Exhibits A-K (the "Declaration"), incorporated by reference into this response in the entirety and specifically paragraphs 2-6.

In the alternative, the *Declaration* evidences that Lindsey and Schenk conceived of the claimed invention prior to the date of publication of the Lindsey references and through continued diligence reduced to practice the claimed invention by filing United States 60/400,486 on July 22, 2010. *See Declaration, paragraphs 2-12.*

Applicant believes the evidence set out in the Declaration is of such character and weight to establish a reduction to practice prior to the publication date of the Lindsey references. Accordingly, the dates within the Exhibits have been redacted and Applicant respectfully requests that the Lindsey references be withdrawn and that any rejection based upon the Lindsey references also be withdrawn.

The Buchanan Reference. Applicant claims the step of staining sperm cells with Hoechst 33342 stain for a period of time of about 25 minutes to about 50 minutes. *Claim 1 as amended.* The Examiner states that Buchanan teaches staining for about 50 minutes. Applicant respectfully disagrees, the Buchanan reference is clear in teaching staining for 60 minutes. *Buchanan, Theriogenology, Abstract and page 1336, last paragraph, and WO '193 at page 36, lines 21-22.* Prior art which teaches a value or range that is very close but does not overlap does not anticipate. *MPEP§2132III.* Applicant's use of the term of approximation "about" in claim 1 certainly does not extend the claimed range to 60 minutes. The specification defines the term "about" in view of incremental embodiments of the invention that can be as close as 10% to the conventional staining time without overlap. *Publication No. 20060067916, Paragraph [0064] and the '486 application.* This would include within 6 minutes of the 1 hour teaching of Buchanan but does not encompass 60 minutes. Applicant's claimed upper limit within the range (50 minutes) is not as close as would be allowed by embodiments of the invention taught in '486 application based on a reduction of time of 10% (54 minutes) that would still remain distinct from the conventional art.

Applicant also claims the step of "incubating said semen prior to staining to maintain temperature above which sperm cell membrane lipids transition from a liquid phase to gel phase of

between about 7°C and about 25 °C”. Applicant makes clear that “incubating” occurs prior to “staining”. The Examiner states that the Buchanan teaches “separating sperm cells comprising incubating the semen at temperatures between 20-25°C”. Applicant respectfully disagrees.

The Buchanan reference does not teach the range as indicated by the Examiner, rather the Buchanan reference generally teaches “room temperature” and “ambient temperature” (Theriogenology, page 1336, first paragraph, and page 1335, last paragraph). These general teachings do not provide any specific example of semen that is necessarily treated within the claimed range or overlapping the claimed range or any points or ranges within the claimed range or suggest any particular advantage for having the semen at ambient temperature or room temperature prior to staining.

Even if the teaching can be construed as including the claimed range of between 20-25 °C as suggested by the Examiner, the Buchanan reference would not anticipate the claimed range. Prior art which teaches overlapping ranges (ambient and room temperature can fall outside of the claimed range) does not anticipate if the prior art does not disclose the claimed range with specificity. *MPEP*§2131.03 II. The question of “sufficient specificity is similar to “clearly envisaging” a species from a generic teaching. *Id.* The general teachings of Buchanan, as above explained do not disclose the claimed range, with the required specificity. Additionally, the Examiner does not provide reasons for the anticipation based on the Buchanan references in accordance with *MPEP*§2131.03 II.

The WO00/06193 Reference. Applicant claims the step of staining sperm cells with Hoechst 33342 stain for a period of time of about 25 minutes to about 50 minutes. *Claim 1 as amended.* The Examiner states that WO00/06193 (the “’193 reference”) teaches staining for about 50 minutes. Applicant respectfully disagrees, the ’193 reference reference is clear in teaching staining for 60 minutes. *WO00/06193 at lines 8-11; page 36 at lines 20-22.* Prior art which teaches a value or range that is very close but does not overlap does not anticipate. *MPEP*§2132III. Applicant’s use of the term of approximation “about” in claim 1 certainly does not extend the claimed range to 60 minutes. The specification defines the term “about” in that the incremental embodiments of the invention could be as close as 10% to the conventional staining

time without overlap. *Publication No. 20060067916, Paragraph [0064]*. This would include within 6 minutes of the 1 hour teaching of the '193 reference but does not encompass 60 minutes. Applicant's claimed upper limit within the range (50 minutes) is not as close as would be allowed by embodiments which would remain distinct from the conventional art set out in the description of the invention (54 minutes).

Also, the Examiner states that '193 reference teaches "separating sperm cells comprising incubating the semen at temperatures between 20-25°C". Applicant respectfully disagrees. Applicant claims the step of "incubating said semen prior to staining to maintain temperature above which sperm cell membrane lipids transition from a liquid phase to gel phase of between about 5°C and about 25 °C". Applicant makes clear that "incubating" occurs prior to "staining".

The '193 reference do not teach the range as indicated by the Examiner, rather the '193 reference generally teaches "room temperature" and "ambient temperature" (WO00/06193 at page 36, lines 15 and 16). These general teachings do not provide any specific example of semen that is necessarily treated within the claimed range or overlapping the claimed range or any points or ranges within the claimed range or suggest any particular advantage for having the semen at ambient temperature or room temperature prior to staining.

Even if the teaching can be construed as "incubating the semen at temperatures between 20-25 °C as suggested by the Examiner, the '193 reference would not anticipate the claimed range. Prior art which teaches overlapping ranges does not anticipate if the prior art does not disclose the claimed range with specificity. *MPEP§2131.03 II*. The question of "sufficient specificity is similar to "clearly envisaging" a species from a generic teaching. *Id*. The general teachings of Buchanan, as above explained do not disclose the claimed range, with the required specificity. Additionally, the Examiner does not provide reasons for the anticipation based on the Buchanan references in accordance with *MPEP§2131.03 II*.

Because the Lindsey references must be withdrawn in view of the Declaration submitted and the Buchanan and '193 references do not teach the claimed time range for staining nor the claimed temperature range for incubation with sufficient specificity to constitute anticipation and

because the Examiner has not provided reasons for the anticipation based on the Buchanan or '193 as required, Applicant respectfully requests that the Section 102 rejection based on Lindsey or either of the Buchanan or '193 references be withdrawn.

4. **The Rejections Under 35 U.S.C.A. Section 103 (a) Are Overcome.** The Examiner has rejected claims 1, 4-12, 15, 16, 18, 21, 151, 154 and 155 under 35 U.S.C.A Section 103(a) as being unpatentable over the combination of each of WO 02/41906 and WO 01/37655 in view of each of Tardif et al. ("Tardiff") and United States Patent No. 6,140,121 to Ellington ("Ellington") supported by Padilla et al ("Padilla"), Johnson ("Johnson"), and Seidel et al ("Seidel").

To reject a claim based on combining prior art elements according to known methods, the office must resolve the Graham factual inquires and provide a finding that the prior art included each element claimed. *MPEP §2143 A (1)*. The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR, 550 US at ___ 82, USPQ2d at 1395*. If any these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *MPEP §2143 A (1)*.

Additionally, "If the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render claims prima facie obvious". *MPEP Rule 2143.01 VI*.

Moreover, "If the proposed modification would render the prior art unsatisfactory for its intended purpose, then there is no motivation to make the proposed modification. *MPEP §2143.01 V*.

The combination of WO'655 in view of each of Tardif and Ellington supported by Padilla, Johnson, and Seidel.

Not All Limitations of the Claimed Invention Are Taught By the Combination.

Firstly, as above remarked the Seidel reference must be withdrawn because it was published after Applicants priority date.

Second, the Examiner indicates that the WO'655 reference teaches "incubating the semen sample at temperatures ranging from 5-25°C (p.10, lines 10-25). *Office Action at Page 7.* Applicant respectfully disagrees.

Applicant claims "incubating said semen prior to staining to maintain temperature above which sperm cell membrane lipids transition from a liquid phase to gel phase of between about 7°C and about 25 °C." *Claim 1 as amended.* The amendment is supported by the specification at Paragraphs [0038] and [0040] and in the priority document Page 15, Example 6 (which provides a series of individual examples in the claimed range which are sufficient to support the range and the amendment). Applicant has amended claim 1 to make clear that the step of incubating occurs prior to the step of staining and that incubating occurs outside of any range taught for handling semen prior to staining taught by the WO'655 reference, as explained below.

The portion of the WO '655 teaching cited by the Examiner does not provide a step corresponding to the claimed incubation step which treats semen prior to staining. Rather, the portion of the WO '655 cited by the Examiner teaches cooling of sperm cells that have already been sex selected by flow cytometry occurring after the claimed steps of staining, determining, separating and collecting as claimed by Applicant. *See WO '655, page 10, lines 12-13.*

Accordingly, the combination of the WO'655 reference with Tardiff (cited for the staining step) and Ellington (as to the addition of caffeine) supported by Padilla and Johnson and Seidel (which must be withdrawn) does not teach the incubating step of claim 1 as amended.

Accordingly, the claimed invention is not obvious in view of the combination of WO'655, Tardiff and Ellington.

The combination of WO'906 in view of each of Tardif and Ellington supported by Padilla, Johnson and Seidel et al.

Firstly, as above remarked the Seidel reference must be withdrawn because it was published after Applicant's priority date.

The Examiner indicates that the WO'906 does not teach staining for a period of 30 minutes. Applicant points out that the WO '906 reference does not teach staining within the claimed time range of "20 minutes to 50 minutes" of claim 1. The WO'906 reference teaches staining "from a lower limit of about 1 hour. . .to about 18, 24, or more hours. . . *WO'906 at page 16, lines 3-7.*

Because WO'906 does not teach the limitation of staining sperm cells for the period of time claimed, the Examiner cites Tardiff as teaching staining sperm cells with Hoechst 33342 for a period of 30 minutes. *Office Action at Page 8.*

No Motivation to Combine the WO '906 and Tardiff Or Johnson References.

However, there would be no motivation to combine the WO'906 reference with Tardiff or Johnson because the proposed modification would change the principle of operation or render the method of the WO'906 reference inoperable.

Firstly, if the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render claims prima facie obvious" *MPEP Rule §2143.01 VI.*

Tardiff teaches as to Experiment 2 (cited by the Examiner) and all other semen processing outside of Experiment 1 that frozen thawed semen are stained with Hoechst 33342 at

37 °C. With respect to Experiment 1 it appears that semen is mixed at 35 °C with TALP buffer (page 202, first column “Semen Extenders and Semen Processing”) and then incubated for 30 minutes at 37 °C (page 202, second column, “Experiment 1”).

Johnson teaches that “after addition of the dye, the sperm are incubated at 32-35°C for less than or equal to 1 hour”. *Johnson at Page 900.*

The purpose behind the method of the WO'906 reference is to entirely avoid treating sperm cells during staining at temperatures as taught by either Tardiff or Johnson. The WO'906 reference teaches that “the use of temperatures in the range of 30 °C to 39 °C in the presence of a QDVS [quantitative DNA vital binding stain] followed by ultraviolet laser based flow cytometry introduces a number of difficulties and disadvantages into the process which begins at semen collection and ends at fertilization which can reduce sperm viability and the efficiency (purity) of sorting sperm into GES [gender enriched semen].” *WO'906 at Page 2, lines 6-18.* Accordingly, WO'906 teaches a “prolonged period of staining. . .at effective temperatures between about the thermotropic phase transition temperature T_m of the membranes of the sperm being sorted up to less than 30 °C . . .to reduce or eliminate the time required for higher temperature incubation with stain. The lower temperatures (compared to the prior art techniques) are also believed to provide advantageous effects on sperm orientation during sorting.” *WO'906 at page 4, lines 28-33 and page 4, lines 1-5.* The “sperm mixture can. . .be incubated for an effective period, for example, from a lower limit of about 1 hour. . .to about 18, 24 or more hours. . .” *WO'906 at page 16, lines 3-7.*

Modifying the WO'906 reference to include the semen handling and staining conditions taught by Tardiff or Johnson (above described in the remarks) would substantially change the principle of operation of the WO'906 reference from that of: maintaining sperm cells between the thermotropic transition temperature up to less than 30 °C and providing a staining period of not less about 1 hour (see also that *WO'906, Table2, shows that a 1.5 hour incubation results in “close to separation” of sperm cells*)) to that of: establishing sperm cells at 32-35 °C and then staining for a period of 30 minutes at 37 °C as taught by Tardiff in Example 1 and Semen Processing), to that of: staining for a period of less than or equal to 1 hour as taught by Johnson

at 32-35°C.

Because modifying the WO '906 teaching to include the staining procedure taught by Tardiff would require a substantial change in the method of the WO '906 reference the claimed invention is not obvious in view of the combination of WO'906, Tardiff and Ellington.

Secondly, "If the proposed modification would render the prior art unsatisfactory for its intended purpose, then there is no motivation to make the proposed modification. *MPEP* §2143.01 V.

By introducing the semen handling and staining conditions taught by Tardiff or Johnson as above described into the method taught by the WO'906, the method taught by the WO'906 reference would be rendered unsatisfactory for its intended purpose of maintaining sperm cells in a narrow range of temperature throughout the semen handling and staining process as above-explained in the remarks of between about the thermotropic phase transition temperature T_m of the membranes of the sperm being sorted up to less than 30 °C.

Additionally, Applicant points out that Tardiff in combination with WO '906 does not provide any teaching of a staining time in the claimed range for the separation of sperm cells into X-chromosome bearing and Y-chromosome bearing populations. Tardiff teaches a period of staining time suitable for analysis of live sperm from dead sperm using computer assisted sperm analysis (CASA). *Tardiff, Abstract*. Accordingly, Tardiff provides only general guidance with respect staining sperm cells and does not provide any specific teaching or guidance as to achieving the claimed invention. *See for example, In re Roemer, 258 F.3d (Fed. Cir. 2000)*. Additionally, the WO'906 teaches away from the staining conditions of Tardiff. WO'906 teaches the use of a "prolonged period of staining. . .at effective temperatures between about the thermotropic phase transition temperature T_m of the membranes of the sperm being sorted up to less than 30 °C . . .to reduce or eliminate the time required for higher temperature incubation with stain. The lower temperatures (compared to the prior art techniques) are also believed to provide advantageous effects on sperm orientation during sorting." *WO'906 at page 4, lines 28-33 and page 4, lines 1-5*. The "sperm mixture can. . .be incubated for an effective period, for

example, from a lower limit of about 1 hour. . .to about 18, 24 or more hours. . .” *WO’906 at page 16, lines 3-7.*

The general guidance with respect to the claimed invention by the combination does not render the claimed invention obvious, especially when the references provide contrary teachings as to how to stain sperm cells for flow cytometry, as above explained in the remarks.

Additionally, Applicant has in the prior response explained that the Johnson reference is a review article which provides only general guidance that Hoechst 33342 can be used to stain sperm cells with the staining time for less than or equal to 1 hour. *Johnson, page 900, first column.* There is no specific teaching or guidance included in the Johnson reference to define with specificity what “for less than or equal to 1 hour” means or to achieve the invention. The guidance is so ambiguous as to not be enabling and does not make the claimed invention obvious. *See for example, In re Roemer, 258 F.3d 1303 (Fed. Cir. 2000).* The teaching can be construed as a range 0 minutes to 60 minutes or construed as 59 minutes to 60 minutes. In the first instance, the range taught is partly inoperative as sperm cells cannot be stained at zero minutes and be separated as claimed (see *WO’906 at Table 2, page 20* and see *Tardiff at page 202, Experiment 1 “only minimal fluorescence at 0 minutes.”*), and at the other extreme, staining for about 1 hour falls outside the claimed range and has all the disadvantages which the claimed invention avoids by discovering a manner of staining sperm cells suitable for use with flow cytometry which takes much less time than 1 hour in the presence of the other claimed limitations which are not taught by Johnson. The ambiguity can be cleared up by support from United States Patent No. 5,135,759 to Johnson which is considered to be enabled, Johnson defines the staining time as being 1 hour at 35 °C. *US5,135,759 at col. 4, lines 40-44.*

Also, if Johnson includes the range of between 0 minutes and 60 minutes, Applicant’s claimed range of 20 minutes to 50 minutes fall within the Johnson range. In that case, Applicant’s claimed range yields unexpected results which fall outside of merely optimizing staining time including “reduce % dead in stained sperm samples or to increase motility, or increase resolution of X-chromosome bearing stained sperm from Y-chromosome bearing stained sperm when flow sorted.” *US 60/400,486 at Pages 14 and 15.* Applicant need not

provide a Declaration in support of these unexpected results because they are set out in the specification itself.

Because the proposed modification would change the principal of operation of the WO '906 reference or render the WO'906 reference unsatisfactory for the intended purpose, and because the references cited in support must be withdrawn, or provide only general guidance, or because the claimed invention yields unexpected results, a case of obvious cannot be established by the combination of WO'906 and Tardiff and Ellington as supported by Padilla, Johnson and Seidal.

Accordingly, Applicant respectfully requests reconsideration of claims 11, 4-12, 15, 16, 18, 21, 150, 151, 154, and 155 and withdrawal of the Section 103(a) rejection based on the combination of WO'906, Tardiff, Ellington, as supported by Johnson.

5. Request For Telephonic Interview. Applicant respectfully requests a telephonic interview with the Examiner to address any remaining concerns that the Examiner may have with respect to the Section 103 concerns.

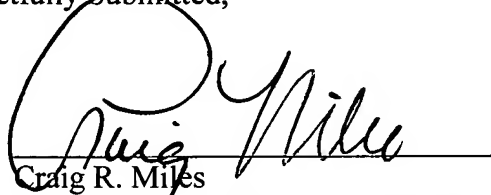
CONCLUSION

Claims 2-4, 13-14, 17, 9-20, 22-149, and 152-153 have been without prejudice canceled. Claim 1 has been amended without the addition of any new matter. Applicant's amendment to claim 1 along with the above remarks overcomes the Section 112, Section 102 and Section 103 concerns raised by the Examiner. Applicant believes that claim 1 as amended and all of the claims made ultimately made dependent on claim 1 are now in condition for allowance and Applicant respectfully requests allowance of same.

Dated this 13 day of December, 2010

Respectfully Submitted,

By:

A handwritten signature in black ink, appearing to read "Craig R. Miles", is written over a horizontal line.

Craig R. Miles

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